AUG 2 3 2000

K001814

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda Compact Airway Module M-CAiOVX and M-COVX (version 01) and accessories

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda, Inc.
3 Highwood Drive
Tewksbury, MA 01876
Tel: 978-640-0460
Fax: 978-640-0469

NAME OF CONTACT:

Mr. Joel Kent
FDA Official Correspondent

DATE:

June 14, 2000

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda Compact Airway Module M-CAiOVX and M-COVX (version 01) and accessories

COMMON NAME:

Airway gas, pressure and volume, anesthetic agent and agent identification and gas exchange measurement device and Airway gas and Patient Spirometry accessories.

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

Analyzer, Gas, Carbon-Dioxide, Gaseous-phase	(per 21 CFR 868.1400)
Analyzer, Gas, Oxygen, Gaseous-phase	(per 21 CFR 868.1720)
Spirometer, Monitoring (W/WO alarm)	(per 21 CFR 868.1850)
Monitor, Airway Pressure (Includes gauge and/or alarm)	(per 21 CFR 868.2600)
Analyzer,Gas,Nitrous-Oxide,Gaseous-phase (Anesthetic conc)	(per 21 CFR 868.1700)
Computer, Oxygen-uptake	(per 21 CFR 868.1730)
Analyzer, Gas, Enflurane, Gaseous-phase (Anesthetic conc.).	(per 21 CFR 868.1500)
Analyzer, Gas, Halothane Gaseous-phase (Anesthetic conc.).	(per 21 CFR 868.1620)

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

Datex-Ohmeda Compact Airway Module M-CAiOVX and M-COVX (version 01) and accessories are subtantially equivalent to two legally marketed devices (predicates). The Datex-Ohmeda Compact Airway Module M-CAiOVX measurement of airway gases (CO2, O2, N2O, anesthetic agents and agent identification) and airway volume, pressure and flow is substantially equivalent to the predicate Datex AS/3™ Compact Airway Module M-CAiOV (K960490) and the gas exchange measurement is substantially equivalent to the predicate CS/3™ Compact Airway Module M-COVX (K982091). The Datex-Ohmeda Compact Airway Module M-COVX (version 01) measurement of airway gases (CO2, O2 and N2O) and airway volume, pressure and flow, and gas exchange measurement is substantially equivalent to the predicate CS/3™ Compact Airway Module M-COVX (version 00, K982091).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The M-CAiOVX and M-COVX (version 01) modules consist of:

* TPX infrared measuring sensor for measuring CO2 and N2O.
* paramagnetic O2 sensor
* Side-Stream Spirometry measurement
* Gas Exchange measurement

The M-CAiOVX's TPX infrared sensor is also capable of measuring anesthetic agents (Enflurane, Halothane, Sevoflurane, Isoflurane and Desflurane).

The modules are assembled in a double width module, which occupies two slots in a Datex-Ohmeda modular monitor frame.

The main accessories include airway gas sampling lines, D-fend water traps, Spirometry measurement tubing and D-lite sensors. See Tab 16 for a complete list of accessories.
The module is first plugged into the frame of the Monitor. The sampling line and the spirometry tube are attached to the module connectors. The monitor is switched on and the gas sampling line and the spirometry tube is attached to the D-lite ™ airway adapter. The D-lite ™ is attached between ventilator Y-piece and Heat and moisture exchanger (HME) of the patient's intubation tube.

The monitor displays measurements from the M-CAiOVX and M-COVX (version 01) modules in the form of numeric values, curves, loops and trends. The monitor also generates audible and visual alarms for this module and indicates the priorities and sources of alarms.

INTENDED USE as required by 807.92(a)(5)

The Datex-Ohmeda Compact Airway Module M-CAiOVX and accessories is indicated for monitoring hospital patient's respiration (CO2, O2, N2O, anesthetic agents, anesthetic agent identification and respiration rate) ventilation (airway pressure, volume and flow) and gas exchange status (Oxygen Consumption VO2, Carbon Dioxide production VCO2, Respiratory Quotient RQ, and Energy Expenditure, EE). Gas exchange status monitoring is not indicated in the presence of N2O+O2 mixtures. The device is indicated for use by qualified medical personnel only.

The Datex-Ohmeda Compact Airway Module M-COVX (version 01) and accessories is indicated for monitoring hospital patient's respiration (CO2, O2, N2O and respiration rate) ventilation (airway pressure, volume and flow) and gas exchange status (Oxygen Consumption VO2, Carbon Dioxide production VCO2, Respiratory Quotient RQ, and Energy Expenditure, EE). Gas exchange status monitoring is not indicated in the presence of anesthetic agents or N2O+O2 mixtures. The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda Compact Airway Module M-CAiOVX measurement of airway gases (CO2, O2, N2O, anesthetic agents and agent identification) and airway volume, pressure and flow is substantially equivalent to the predicate Datex AS/3™ Compact Airway Module M-CAiOV (K960490) and the gas exchange measurement is substantially equivalent to the predicate CS/3™ Compact Airway Module M-COVX (K982091). The M-CAiOVX compared to predicates, M-CAiOV (K960490) and predicate M-COVX (version 00, K982091), are nearly identical in all respects with the exception of the following differences: minor sampling system differences, small changes to the gas exchange specifications, the spirometry keyboard has been added to the M-CAiOVX, the CO2 absorber has been added to the zero input of the M-CAiOVX , an additional D-Lite+ accessory is now available and small changes to the gas exchange specifications. These changes do not effect safety and effectiveness as compared to the predicates.

The Datex-Ohmeda Compact Airway Module M-COVX (version 01) measurement of airway gases (CO2, O2 and N2O) and airway volume, pressure and flow, and gas exchange measurement is substantially equivalent to the predicate CS/3™ Compact Airway Module M-COVX (version 00, K982091). The M-COVX (version 01) compared to the predicate predicate M-COVX (version 00, K982091) I nearly identical except for the following differences: The spirometry keyboard has been added to the M-COVX (version 01), small changes to the gas exchange specifications, the CO2 absorber has been added to the zero input of the M-COVX (version 01) and an additional D-Lite+ accessory is now available. These changes do not effect safety and effectiveness as compared to the predicate.

Based on the above analysis and other documentation included in this 510(k) notification and attachments, it is evident that the main features and indications for use of the Datex-Ohmeda Compact Airway Module M-CAiOVX and M-COVX (version 01) and accessories is substantially equivalent to the predicates Datex AS/3™ Compact Airway Module M-CAiOV (K960490) and the gas exchange measurement is substantially equivalent to the predicate CS/3™ Compact Airway Module M-COVX (version 00, K982091). The comparison above as well as supporting data and analysis shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda Compact Airway Modules M-CAiOVX and M-COVX (version 01) and accessories.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda Compact Airway Module M-CAiOVX and M-COVX (version 01) and accessories is in compliance with safety standards and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance to the following mandatory and voluntary standards have been made:

- IEC 601-1:1988+Amdt 1:1991+Amdt 2:1995
- EN 60601-1: 1990+A1:1993+A2:1995+A13:1996
- CAN/CSA-C22.2 No. 601.1-M90 +S1:1994+Amdt2:1998
- ISO 9918:1993
- EN 864:1996
- ISO 7767:1997
- EN 12598:1999
- ISO 11196:1995 + Corr. 1:1997 /EN ISO 19996 (1997)
- ASTM F-1456 (1992) Standard specification for Capnometers
- ASTM F-1462 (1993) Specification for Oxygen analyzers

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda Compact Airway Module M-CAiOVX and M-COVX (version 01) and accessories as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 23 2000

Mr. Joel C. Kent
Datex-Ohmeda, Inc.
Three Highwood Drive
Tewksbury, MA 01876

Re: K001814
Datex-Ohmeda Compact Airway Module M-CAiOVX and M-COVX (version 01) and accessories
Regulatory Class: II (two)
Product Code: CCK, CCL, BZK, CAP, CBR, BZL, CBQ, CBS
Dated: June 14, 2000
Received: June 15, 2000

Dear Mr. Kent:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001814

Device Name: **Datex-Ohmeda Compact Airway Module M-CAiOVX and M-COVX (version 01) and accessories**

The Datex-Ohmeda Compact Airway Module M-CAiOVX and accessories is indicated for monitoring hospital patient's respiration (CO2, O2, N2O, anesthetic agents, anesthetic agent identification and respiration rate) ventilation (airway pressure, volume and flow) and gas exchange status (Oxygen Consumption VO2, Carbon Dioxide production VCO2, Respiratory Quotient RQ, and Energy Expenditure, EE). Gas exchange status monitoring is not indicated in the presence of N2O+O2 mixtures. The device is indicated for use by qualified medical personnel only.

The Datex-Ohmeda Compact Airway Module M-COVX (version 01) and accessories is indicated for monitoring hospital patient's respiration (CO2, O2, N2O and respiration rate) ventilation (airway pressure, volume and flow) and gas exchange status (Oxygen Consumption VO2, Carbon Dioxide production VCO2, Respiratory Quotient RQ, and Energy Expenditure, EE). Gas exchange status monitoring is not indicated in the presence of anesthetic agents or N2O+O2 mixtures. The device is indicated for use by qualified medical personnel only.

for Mark N Milhern

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001814

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)